

peripheral vascular disorders, multiple sclerosis, amyotrophic lateral disorders, amyotonia congenita, Parkinson's disease, ascending lateral sclerosis, anterior poliomyelitis, liver disease, diabetes, hypothyroidism and atherosclerosis.

DISPOSITION: 2-28-62. Default—destruction.

6809. Vitamin B₁₂ injection. (F.D.C. No. 46064. S. No. 57-220 R.)

QUANTITY: 2 ctns., each containing 500 individually ctnd. vials, at Long Island City, N.Y.

SHIPPED: 4-27-61, from Baltimore, Md., by Bio Ramo Drug Co., Inc.

LABEL IN PART: (Vial and ctn.) "10 cc. Crystalline Vitamin B₁₂ Injection U.S.P. 30 mcg. crystalline Vitamin B₁₂ per cc. * * * Usual Dose: * * * (see insert) Control: 04131 Bio Ramo Drug Co., Inc., Baltimore 1, Md."

ACCOMPANYING LABELING: Leaflets entitled "Vitamin B₁₂ Injection."

LIBELED: 7-10-61, E. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for sensory neuropathies, trigeminal neuralgia (tic douloureux), diabetic neuritis, alcoholic neuritis, and other neuritides.

DISPOSITION: 8-29-61. Default—destruction.

6810. Sulf-Hydro-Sol and S-M-C (Sulfur Mineral Concentrate). (F.D.C. No. 46266. S. Nos. 54-452/3 R.)

QUANTITY: 311 1-oz. btls. and 132 2-oz. btls. of *Sulf-Hydro-Sol* and 8 1-pt. btls. of *S-M-C* (*Sulfur Mineral Concentrate*), at Minneapolis, Minn.

SHIPPED: 7-19-61, from Salt Lake City, Utah, by Colloidal Sulphur Co., Inc.

LABEL IN PART: "Pavo * * * Sulphur Sulf-Hydro-Sol Mixture An Exceptional Non-Toxic colloidal sulphur mixture containing as active ingredients Highly reactive sulphur complexes and colloidal trace minerals, in a high potency concentrate supplying the univalent radical SH. Directions: 6 to 10 drops in water * * * before meals * * * The Pavo Co., Inc., Minneapolis, Minn." and "Pavo * * * Sulphur-Mineral S-M-C Concentrate S-M-C Colloidal Sulphur—for Bath and External use only—Contains: Calcium Polysulfides, Mono-sulphide, Thiosulphate, Sulphate and Polysulfide Sulfur. Directions: * * * S-M-C is a new and effective preparation which brings the benefits of the world's outstanding sulfur mineral baths into your own home in a highly concentrated form. * * * The Pavo Co., Inc., Minneapolis, Minn."

ACCOMPANYING LABELING: Leaflets entitled "A Modern Spa In Your Home," and imprinted at the bottom "The Colloidal Sulphur Company, Incorporated, William A. Caudill, President, 599 Columbus Street, Salt Lake City 16, Utah."

LIBELED: 8-31-61, Dist. Minn.; amended libel 9-12-61.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles, when used as directed, were adequate and effective as a treatment for rheumatoid arthritis, and certain metabolic diseases due to sulfur deficiency; and that use of the articles would stimulate metabolism, revitalize and normalize cellular metabolism, and that one could bathe and drink his way to health and beauty by use of the articles; and that *Sulf-Hydro-Sol* possessed therapeutic and special dietary properties due to the presence therein of highly

reactive sulfur complexes and colloidal trace minerals in a high potency concentrate supplying the univalent radical SH.

DISPOSITION: 10-31-61. Default—destruction.

6811. Ease diuretic tablets. (F.D.C. No. 46346. S. No. 19-801 T.)

QUANTITY: 797 112-tablet btls. at Fort Worth, Tex., in possession of Rhodes Laboratory.

SHIPPED: 6-29-61, from Bell Gardens, Calif., by Boyle & Co. Pharmaceuticals.

LABEL IN PART: "Ease Tablets A Stimulant Diuretic * * * Distributed Exclusively by Rhodes Laboratory, Ft. Worth, Texas * * * Contains Theobromine Sodium Salicylate, Oleoresin, Capsicum, Extract Buchu, Extract Uva Ursi, Extract Juniper Berries."

ACCOMPANYING LABELING: Radio scripts entitled "5 Minute Commercial," "Ease Commercial Script Hazel," and "Ease Script Alarm Alert"; and a number of Rhodes Laboratory letterheads containing testimonials, which were used in promoting sales of the article.

LIBELED: 9-28-61, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for backache, leg pains, rheumatic and arthritic stiffness, headaches, dizziness, nervousness, puffiness under the eyes, swelling ankles, hands, arms, and feet, excess poisonous matter in the blood, malfunction of the kidneys, bloat, bladder urgency, neuralgia, cramps, and excess weight.

DISPOSITION: 4-27-62. Consent—destruction.

6812. Cholester-Sol capsules. (F.D.C. No. 46475. S. No. 95-721 R.)

QUANTITY: 7 8,000-capsule drums, 1 3,500-capsule drum, 28 100-capsule btls., and 3 1,000-capsule btls., at Houston, Tex., in possession of Merit Pharmaceutical Co., Inc.

SHIPPED: 5-17-61, from Detroit, Mich.

LABEL IN PART: (Btl.) "Cholester-Sol 3 Capsules Contain: Choline Bitartrate 375 mg. Inositol 75 mg. DL-Methionine 150 mg. Liver Desiccated 150 mg. Unsaturated Fatty Acids 150 mg. Vitamin B-12 USP 1.5 mcg. L-Lysine Monohydrochloride 300 mg. Vitamin C (Ascorbic Acid) 75 mg. Manufactured for Merit Pharmaceutical Company, Inc."

ACCOMPANYING LABELING: File cards entitled "Cholester-Sol Lipotropic" and reading in part, "A modern therapy for use in control of hypercholesterolemia"; and a number of repack bottle labels.

RESULTS OF INVESTIGATION: The article in the bottles was repacked and labeled by the dealer from bulk stock shipped as described above.

The file cards were printed locally on order of the dealer.

LIBELED: 10-2-61, S. Dist. Tex.

CHARGE: 502(a)—while held for sale, the name of the article "*Cholester-Sol capsules*," and statements in its labeling, were false and misleading in that they represented and suggested that the article was adequate and effective for the control of hypercholesterolemia and atherosclerosis; to reverse fatty infiltration of the liver and to prevent hepatic cell destruction; stimulate regeneration of new liver cells and generally improve liver function; increase protein utilization (make animal protein of cereal protein); for the treatment of